to 100 mg every 24 hours, (n=24). The source of the curve is the label from the ~~Kadian®~~ KADIAN® commercial product.

Please amend paragraphs between lines 25-37 on page 51 to lines 1-6 of page 52 of the application as filed, as follows:

The result of the study are shown in Fig. 4. In Fig. 4 is also included data for a comparative composition, ~~Dolcontin~~ DOLCONTIN®. The results indicate that the shape as well as the size of the composition is important.

Another clinical study has also been performed as a phase II, open, prospective, controlled study in patients with chronic pain. The study included 13 patients with chronic pain for any reason judged by the investigator as stable and in need of opioids analgesics. A composition according to the invention was tested and compared with a commercially available morphine containing composition, ~~Dolcontin~~ DOLCONTIN®. The total morphine sulphate released from the composition according to the invention was about 20 mg (the dosage in ~~Dolcontin~~ DOLCONTIN® was 30 mg). Although there was a difference in the amount administered, it was evident from the study that the therapeutic effect of a composition according to the invention was not different from ~~Dolcontin~~ DOLCONTIN®, i.e. a reduction is the overall dose may be reduced by the use a zero order release composition. Moreover, the adverse effects reported were less compared to the ~~Dolcontin~~ DOLCONTIN® composition, most likely due to the smaller amount of morphine sulphate administered. Another interesting feature is that during the study rescue medication was allowed and there was no difference in the intake of rescue medicine of patients administered with ~~Dolcontin~~ DOLCONTIN® or with a composition according to the invention. FIG. 5 shows the plasma concentration versus time profiles from the study.

Please amend paragraph between lines 24-25 on page 55 of the application as filed, as follows:

Objective: To compare the pharmacokinetic profile of ~~Morphine Sulphate Egalet®~~ EGALET® Morphine Sulphate 30 mg with that of a reference product, MST ~~Continus®~~ CONTINUS® 30 mg tablets, in healthy male volunteers.

Please amend bridging paragraph between pages 55-56 of the application as filed, as follows:

Test drug ~~Morphine Sulphate Egalet®~~ EGALET® Morphine Sulphate 30 mg controlled release formulation, 1 x 30 mg, Batch 03-0005-066 (Example 6, Conus 1). Reference drug: MST ~~Continus®~~ CONTINUS® 30 mg tablet 1 x 30 mg, Batch 110881. Test for content of test and reference drug after finalizing clinical study and study report demonstrated that the content of the test drug was 12% lower than the reference drug. The result is not corrected for that difference in Table B.

Please amend paragraph between lines 20-22 on page 59 of the application as filed, as follows:

Objective: To compare the pharmacokinetic profile of ~~Morphine Sulphate Egalet®~~ EGALET® Morphine Sulphate 30 mg in fasted and fed state with that of a reference product, MST ~~Continus®~~ CONTINUS® 30 mg tablets, in healthy volunteers.

Please amend paragraph between lines 27-29 on page 59 of the application as filed, as follows:

Test drug ~~Morphine Sulphate Egalet®~~ EGALET® Morphine Sulphate 30 mg controlled release formulation, 1 x 30 mg, Batch 03-0062-066.

Reference drug: MST ~~Continus®~~ CONTINUS® 30 mg film coated tablet 1 x 30 mg.